

EXHIBIT 4

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

C.A. No. 21-1015 (JLH)

SAREPTA THERAPEUTICS, INC. and
THE UNIVERSITY OF WESTERN
AUSTRALIA,

Defendant/Counter-Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD.
and NS PHARMA, INC.

Plaintiff/Counter-Defendants.

EXHIBIT 4

**SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN
AUSTRALIA'S DISPUTED FACTS FOR AFFIRMATIVE CASE**

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In accordance with Local Rule 16.3(c) of the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, Sarepta Therapeutics, Inc. (“Sarepta”) and the University of Western Australia (“UWA”) (collectively, “Counter-Plaintiffs”) provide a statement of the facts which Counter-Plaintiffs contend remain to be litigated.

By setting forth specific information herein, Counter-Plaintiffs do not intend to waive their right to prove information not specifically set forth herein. This statement is not intended to be exhaustive and, in addition to what is set out herein, Counter-Plaintiffs may prove any matters identified in their pleadings and discovery taken in this action to date.

The following statement is based on the parties’ pleadings, documentary and testimony evidence, expert reports, and on Counter-Plaintiffs’ current understanding of Nippon Shinyaku Co., Ltd.’s (“NS Japan”) and NS Pharma, Inc.’s (“NS Pharma”) (collectively, “Counter-Defendants”) claims and/or defenses. Counter-Plaintiffs reserve the right to revise, amend, supplement, or modify the following statement based on any pretrial rulings by the Court and/or to address any additional issues, arguments raised by Counter-Defendants, evidence, or other developments in the case, including edits to the draft pretrial order, any meet and confers or other negotiations between the parties, pending motions, and similar developments. To the extent that Counter-Plaintiffs’ Statement of Issues of Law to be Litigated set forth in Exhibit 6 contains issues of fact, those issues are incorporated herein by reference. Should the Court determine that any issue identified below is more appropriately considered an issue of law, Counter-Plaintiffs incorporate such issue by reference in Exhibit 6.

I. INFRINGEMENT OF THE WILTON PATENT

A. U.S. Patent No. 9,994,851

1. After the original Pretrial Order was filed, the Court granted Counter-Plaintiffs' Motion for Summary Judgment of Infringement of U.S. Patent No. 9,994,851 ("the '851 Patent" or the "Wilton Patent"), specifically including the asserted claim 1 of that patent. D.I. 541 at 5. Thus, NS Japan and NS Pharma's infringement of the asserted claim is no longer a disputed fact.

II. DAMAGES FOR COUNTER-DEFENDANTS' INFRINGEMENT OF THE WILTON PATENT

2. The amount of damages in the form of lost profits to which Counter-Plaintiffs are entitled, as proven by a preponderance of the evidence, to compensate for Counter-Defendants' infringement of the Asserted Claim of the Wilton Patent.

3. The amount of damages in the form of a reasonable royalty to which Counter-Plaintiffs are entitled, as proven by a preponderance of the evidence, to compensate for Counter-Defendants' infringement of the Asserted Claim of the Wilton Patent.

4. Whether Counter-Plaintiffs have proven by a preponderance of evidence that Counter-Defendants willfully infringed the Asserted Claim of the Wilton Patent.

5. Whether Counter-Plaintiffs are entitled to enhanced damages, which is for the Court to determine post-trial, and on which the parties will submit briefing during post-trial motions.

6. Whether this case is exceptional and Counter-Plaintiffs should be awarded attorneys' fees, which is for the Court to determine post-trial, and on which the parties will submit briefing during post-trial motions.

7. The rate of prejudgment interest to which Counter-Plaintiffs are entitled and whether it should be compounded, which are issues for the Court to determine after trial, and on which the parties will submit briefing during post-trial motions.

8. The costs to which Counter-Plaintiffs are entitled, which is for the Court to determine post-trial, and on which the parties will submit briefing during post-trial motions.

III. INVALIDITY OF THE NS PATENTS¹

A. Person of Ordinary Skill in the Art (“POSA”) as of August 31, 2011

9. The qualification and experience of a POSA.

B. Obviousness Under 35 U.S.C. § 103

10. Whether Sarepta has established by clear and convincing evidence that claim 3 of the ’092 Patent is invalid as obvious.

11. Whether Sarepta has established by clear and convincing evidence that claim 2 of the ’461 Patent is invalid as obvious.

12. Whether Sarepta has established by clear and convincing evidence that claim 1 of the ’106 Patent is invalid as obvious.

13. Whether Sarepta has established by clear and convincing evidence that claim 3 of the ’741 Patent is invalid as obvious.

14. Whether Sarepta has established by clear and convincing evidence that claim 4 of the ’217 Patent is invalid as obvious.

15. The scope and content of the prior art.

16. The level of ordinary skill in the art as of August 31, 2011.

17. The differences, if any, between: (1) the subject matter claimed by the NS Patents; and (2) the following prior art references, alone or in combination:

- Popplewell et al., “Comparative Analysis of Antisense Oligonucleotide Sequences Targeting Exon 53 of the Human *DMD* Gene: Implications for Future Clinical Trials,” *Neuromuscul. Disord.* (2010) 20(2):102-110 (“Popplewell 2010”);

¹ The NS Patents refer to U.S. Patent Nos. 10,385,092; 10,407,461; 10,487,106; 10,647,741; and 10,662,217.

- Sazani et al., “Safety Pharmacology and Genotoxicity Evaluation of AVI-4658,” Int. J. Toxicol. (2010) 29(2):143-156 (“Sazani 2010”); and
- Reeves et al., International Patent Publication No. WO 2009/064471 (“Reeves PCT ’471”).

18. Whether, in view of the prior art as a whole and the general knowledge in the art, a POSA would have had a reason to modify or combine the teachings of the prior art listed above to obtain the subject matter claimed by the NS Patents with a reasonable expectation of success.

19. Whether, in view of a design need or market pressure to solve a problem and a finite number of identified, predictable solutions in the prior art, the subject matter claimed by the NS Patents would have been obvious to try.

20. Whether there is a nexus between the subject matter claimed by the NS Patents and any alleged objective indicia of nonobviousness, including commercial success, failure of others, long felt unmet need, industry praise, and unexpected results.

21. Whether near simultaneous invention by other researchers of the subject matter claimed by the NS Patents indicates that the subject matter would have been obvious to a POSA.